

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 9, 2009 has been entered.

Amendment Entry

2. The amendment filed June 9, 2009 has been entered. Claims 71,-72, and 81 have been amended. Claims 1-43, 45-47, 52-53, 62-63, 66-70, 73, 76 and 79-80 have been canceled. Claim 87 has been newly added. Claims 44, 48-51, 54-61, 64-65, 71-72, 74-78 and 81-87 are under consideration in this application.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments and declarations:

a) The objection of claims 71-72 and 76;

b) The new matter rejection of claims 60, 73, 76, 7 and 81 under 35 U.S.C. 112, first paragraph; and

b) The rejection of claims 44, 47-61, 64-65, 67 and 71-80 under 35 U.S.C. 103(a) as being unpatentable over Geng et al., in view of Little et al.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Paul Booth on August 12, 2009.

The application has been amended as follows: Claim 61 (Currently Amended)
A method for quantifying the amount of a peptide in a biological sample, comprising:
contacting the sample with (i) an anti-peptide antibody specific for said peptide; (ii) a known quantity of a labeled version of the peptide, separating peptides bound by said antibody from unbound peptides eluting said peptide bound by said antibody from said antibody; measuring the amount of the peptide eluted from said antibody using a mass spectrometer; and calculating the amount of the peptide in the biological sample;
wherein said biological sample is a proteolytic digest of a bodily fluid.

Allowable Subject Matter

5. Claims 44, 48-51, 54-61, 64-65, 71-75, 77-78, and 81-87 are allowed.

6. The following is an examiner's statement of reasons for allowance: The declarations of record demonstrate that it was unexpected that mass spectrometric suitable proteolytic fragments could be effectively isolated from a complex biological proteolytic digest by antibodies. The declarations recite that the surprising and unexpected results drawn to the proteolytic digests are complex and contain the desired peptides, often at very low concentrations in the presence of a huge number of extraneous peptides. That being the case, any antibody must also have a suitably high affinity for that peptide so that it can specifically bind the peptide in the presence of huge numbers of competing peptides present at much higher concentrations. Furthermore, proteolysis of peptides has been shown to lead to detection difficulties when antibodies against proteolytically cleaved regions are used. The prior art does not teach or suggest the use of anti-peptide antibodies specific for the first and second peptides for the isolation of peptides from a proteolytic digest of a biological sample prior to being detected by mass spectrometric analysis.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/

Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645